



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/807,974

03/24/2004

Charles C. Hart

A-3124-AL

6970

21378

7590

05/15/2009

APPLIED MEDICAL RESOURCES CORPORATION

22872 Avenida Empresa

Rancho Santa Margarita, CA 92688

EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,974	Applicant(s) HART ET AL.	
	Examiner BHISMA MEHTA	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 48-76 is/are pending in the application.
- 4a) Of the above claim(s) 10-19, 27-33 and 48-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 20-26, 34-38, 75 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7 2009 has been entered.

Election/Restrictions

2. Newly submitted claims 73 and 74 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly filed claims 73 and 74 are withdrawn as being drawn to a non-elected species as the elastomeric sheet comprising a generally planar profile or a generally conical profile is not shown in the elected species (Species A - Figures 6-10). Specifically, it is not disclosed or shown that the elastomeric sheet of the septum seal comprises a generally planar profile or a generally conical profile.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 73 and 74 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9, 20-26, 34-38, 75, and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The septum seal comprising an aperture through the elastomeric sheet was not disclosed in the specification as originally filed. There is disclosure in the specification for the elastomeric sheet having a hole or a piercing. The specific wording of "aperture" can also be used to define a small opening, a natural opening, or a slit. These definitions are not all considered to be consistent with a hole or a piercing.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9, 20-24, 34-38, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Steigerwald

Art Unit: 3767

(U.S. Patent No. 4,895,346). Lafontaine disclose a surgical access device having an elongate tubular member (110), a polymeric septum seal (140) formed at the distal end of the tubular member, and a zero seal (130) disposed at the distal end of the tubular member and distal to the septum seal. The septum seal has an aperture in the form of a hole or piercing which is configured to receive an instrument. The zero seal is coupled to the septum seal and has properties to float with the septum seal relative to the tubular member. Lafontaine discloses the surgical access device substantially as claimed. However, Lafontaine is silent to the specifics of the septum seal comprising an elastomeric sheet having an aperture through the elastomeric sheet. Steigerwald discloses a surgical access device having a septum seal (76) comprising an elastomeric sheet and an aperture through the elastomeric sheet (Figure 1 and lines 12-45 of column 3) and a zero seal (82) distal to the septum seal which is sized and configured to seal when no instrument is present. The aperture is in the form of a hole or piercing which is configured to receive an instrument. Steigewald also discloses another embodiment for a septum seal as seen in Figure 11 (lines 46-63 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal of Steigerwald as both Lafontaine and Steigerwald disclose surgical access devices having two seals to ensure that a fluid tight seal is achieved when an instrument is placed through the seals (lines 46-64 of column 4 of Lafontaine and lines 20-48 of column 4 of Steigerwald) and Steigerwald teaches that this fluid-tight seal can also be achieved with a septum seal comprising an elastomeric sheet and an aperture.

As to claim 2, see lines 5-20 of column 3. As to claims 3 and 4, the zero seal is a duckbill seal with an intersecting sealing portion (134A) or a double duckbill seal with two or more intersecting sealing portions (134B). As to claims 5 and 6, see Figure 3. As to claims 7-9, see lines 6-22 of column 4. The device also has a placement device (14, 40, 50). As to claim 21, the placement device is an obturator. As to claim 22, the placement device includes an elongate shaft with a proximal end, a mid-portion, and a distal end. As to claim 23, the proximal end of the elongate shaft has a handle and the mid-portion of the elongate shaft has a reduced profile (see Figure 1). As to claim 34, the seal has opposing lip portions (132) separated by a slit portion. As to claims 35 and 36, see lines 31-46 of column 4. As to claims 37 and 38, the lip portions are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

7. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Steigerwald as applied to claim 22 above, and further in view of Green et al (U.S. Patent 6,497,716). Lafontaine in view of Steigerwald disclose the device substantially as claimed. However, Lafontaine is silent on the specifics of the distal end of the placement device being shaped like an hourglass or comprising a tapered, cone-shaped member. Green et al disclose a placement device (22) which is used to place an access device (14) where the distal end of the placement device is shaped like an hourglass and has a tapered, cone-shaped member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the placement device of Lafontaine with the placement device of Green et al

Art Unit: 3767

as both Lafontaine and Green et al disclose surgical access devices and placement devices for placing the access devices and Green et al disclose that it is well known to use a placement device having a distal end shaped like an hourglass and a tapered, cone-shaped member to place the access device.

Response to Arguments

8. Applicant's arguments with respect to claims 1-9, 20-24, 34-38, 75, and 76 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Application/Control Number: 10/807,974

Page 7

Art Unit: 3767

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767